

Recommendations of the SEC (Ophthalmology) made in its 57th meeting held on 01.09.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000043 Lifitegrast Oph. Sol. 5%	M/s. Ajanta	In light of earlier SEC recommendation dated 26.05.2022 the firm presented revised protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented subject to the condition that the firm should define the volume of the drop i.e. one drop per eye.
Biological Division			
2.	BIO/IMP/22/000042 Brolucizumab	M/s. Sandoz	The firm presented their proposal for grant of permission of additional indication for the treatment of Diabetic Macular Edema (DME) for already approved drug Brolucizumab Solution for Injection 120 mg/ml in vial + filter needle. The firm presented the data of 24 Indian patients from ongoing Phase III global clinical trial (KITE) in the proposed indication out of 360 total global patient populations. After detailed deliberation, the committee opined that the presented data is inadequate and recommended that the firm should conduct adequate powered Phase III study in Indian population to generate more efficacy and safety data.
3.	BIO/CT04/FF/2022/29916 Bevacizumab	M/s. Reliance Life Sciences	The firm presented the protocol-‘A prospective, multi-center, randomized, open label, two-arm, parallel group, active control, comparative Phase II / Phase III clinical study to evaluate efficacy and safety of R-TPR-023 / Lucentis® in patients with neovascular (wet) age-related macular degeneration’. The committee noted that the drug is not approved for the proposed indication and the firm has completed the pre-clinical toxicity studies. After detailed deliberation, the committee recommended that the firm should

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			<p>conduct Phase I clinical study initially.</p> <p>Accordingly, the firm should submit Phase I protocol for further deliberation.</p> <p>Note: Dr.Somesh Aggarwal did not participate in the deliberation.</p>
SND Division			
4.	<p>SND/MA/21/000499</p> <p>Atropine Sulfate Ophthalmic Solution 0.01% w/v Stabilised Oxychloro complex 0.005% w/v (SOC) as preservative (Change in preservative)</p>	M/s. Indiana Ophthalmic	<p>The firm presented proposal for grant of permission for manufacturing and marketing of Atropine Sulfate Ophthalmic Solution 0.01% w/v Stabilised Oxychloro complex 0.005% w/v (SOC) as preservative.</p> <p>After detailed deliberation, the committee recommended that the firm should submit Ocular toxicity data for proposed formulation for further review by the committee.</p>
FDC Division			
5.	<p>FDC/CT/20/000071</p> <p>Tropicamide 0.2mg/ml + Phenylephrine HCl 3.1mg/ml + Lidocaine HCL 10mg/ml Solution for injection</p>	M/s. Entod Pharmaceuticals	<p>In light of earlier SEC recommendation dated 22.09.2021, the firm presented complete Phase IV CT study report before the committee.</p> <p>After detailed deliberation, the committee recommended for considering continued manufacture & marketing of the product.</p>
6.	<p>FDC/MA/21/000132</p> <p>Tropicamide 0.2mg/ml + Phenylephrine HCl 3.1mg/ml + Lidocaine HCL 10mg/ml Solution for injection</p>	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
Medical Device Division			
7.	<p>CI/MD/2022/52586</p> <p>AT LISA809M/M</p>	M/s. Clinexel Life Sciences Private Limited	<p>The firm presented their proposal to conduct post market clinical investigation before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the said study on Indian population.</p>
8.	<p>IMP/MD/2022/53770,</p> <p>IMP/MD/2022/53773,</p> <p>IMP/MD/2022/53775,</p>	M/s. Hoya Medical India Pvt. Ltd.	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee</p>

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	IMP/MD/2022/53779 (Form MD-14) Vivinex Gemetric, Vivinex Gemetricplus, Vivinex Gemetric Toric, Vivinex Gemetric plus Toric (Intraocular Lens)		recommended for grant of permission to import & market the proposed products (Vivinex Gemetric, Vivinex Gemetricplus, Vivinex Gemetric Toric, Vivinex Gemetric plus Toric) in India with the condition that the firm should submit PMS data of first 50 patients to CDSCO.